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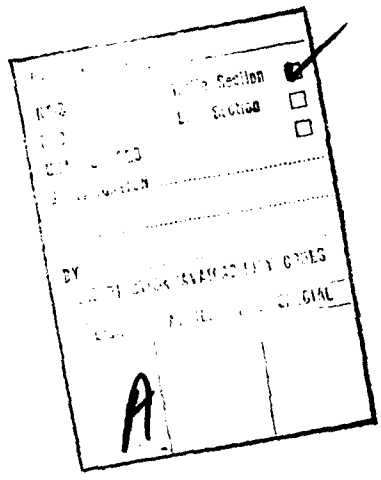

EVALUATION OF ENDODONTIC INSTRUMENTS AS RECEIVED FROM THE MANUFACTURER: THE DEMAND FOR QUALITY CONTROL

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ABSTRACT

Two hundred seventy new files, reamers and Hedstrom files from three different manufacturers were evaluated for debris and defects. Statistical analysis of the new instruments showed that one company's instruments were cleaner than the other two but still contained defects. A standard for quality is proposed.

In recent years there has been much discussion concerning standardized and non-standardized instruments and its importance. Much has been written about the poor compliance of the manufacturers of endodontic instruments concerning standardization. However, to this date little has been written concerning the quality control of debris and defects of our intracanal instruments when received from the manufacturer. It is important to consider debris on new instruments since prior to sterilization all organic debris must be removed.[1] Defects in instruments may preclude untwisting of the instruments, or blockage of the canal due to fracture of the instrument.

Unfortunately, no current information exists about the condition of reamers and files obtained from the manufacturer. Thus the purpose of the present study was to evaluate the degree of debris in newly manufactured intracanal instruments and to study their possible defects.

METHODS AND MATERIALS

This study evaluated 270 new instruments (thirty files, thirty reamers, and thirty Hedstrom files) from three different companies still in their original packages. All instruments were standard size 25. A holder especially fabricated to resist movement of the files while being examined was used. This holder consisted of a pin protruding from a platform with a millimeter rule attached for a reference point (Fig. 1). The hole of manufacture origin placed in the plastic handle was used to position the instrument on the holder. The instrument size number or a notch placed in the handle with a hot instrument was used to orient the file or reamer blade so that only one surface was constantly examined.

All instruments were handled only by the plastic handle. At no

time was the instrument blade touched. The new files and reamers were examined under a stereomicroscope at 37.5 times magnification. The amount of debris on each instrument was rated on a scale from one to four. A score of four represented an instrument that was severely coated with debris. A score of one represented an instrument completely free of debris. Scores were statistically compared using the Chi-square technique and the method of Cochran.[2]

RESULTS

Observation of the amount of debris recorded on the new instruments indicated that none of the 270 instruments could be considered clean after removal from its package. These data are shown in Table I.

The data obtained on new instruments were arranged in a 9 by 2 contingency table and subjected to Chi-square analysis. Because of the small numbers of severely coated specimens, they were combined with the moderately coated group for purposes of statistical analysis. There were no clean specimens. Results of analysis yielded a significant Chi-square (x^2=45.34; df=8; p=<.001) indicating that differences existed among manufacturers. In order to determine the source of the differences the data were partitioned according to the method of Cochran[2] and the results of the analysis revealed that company A's files, reamers, and Hedstrom files were significantly freer of debris then the other manufacturers (x^2=15.11; df=2; p=<.001).

It was observed that company C's instruments had a much greater amount of colloidal debris and a grease or an oil film present (Fig. 2). Plastic from the handle was another common finding within the flutes (Fig. 3). Two Hedstrom files from two different manufacturers had a

section of foam rubber entwined within the flutes (Fig. 4). Other instruments appeared to have epithelial cells within the flutes, possibly from a worker handling the blade of the instrument (Fig. 5).

Metal spurs appeared to be frequent in all three companies, although more so in files than reamers or Hedstrom files (Fig. 6). Hedstrom files frequently nad barbs at their tips (Fig. 7). Other common defects in the instruments were sections of flutes which were either observed to be unwound slightly or wound too tightly. This was seen commonly with the files (Fig. 8). Comparison of similar instruments from the three different manufacturers showed noticeable differences in the space between the flutes and the apparent sharpness of the instruments (Fig. 9).

DISCUSSION

Evaluation of 270 files, reamers, and Hedstrom files directly out of their packages demonstrated the need to cleanse these instruments prior to being autoclaved. Unfortunately cleansing is extremely difficult and quite time consuming. The plastic and metal spurs represent perhaps the most serious debris. Both have the potential to cause spontaneous blockage of fine radicular canals. Eventual corrosion of the dislodged metal spurs may cause complications; the possibility of which have not been fully investigated.

The amount of plastic found within the flutes was extremely large and quite common. Fortunately, the larger bulk of plastic debris was easily dislodged with gauze wipes used in a twisting motion. This method of cleaning, however did not usually remove all the plastic within the flutes. Ultrasonic solutions had no effect on the majority of the plastic debris. The salt sterilizer was used in an attempt to melt the

plastic within the flutes. It did not accomplish this but left the flutes coated with salt crystals (Fig.10).

It would appear from our evaluation of new files and reamers that some improvement of quality control needs to be implemented by the manufacturers. This quality control must include compliance with the AAE standardization code as well as elimination of defects in the instruments and the debris that was found to be present.

SUMMARY

270 new files, reamers and Hedstrom files from three different companies were examined for debris and defects. Though statistical analysis showed that the instruments from one company were freer of debris; these same instruments will contain some defects. A suggestion for standards of quality control concerning debris and defects is suggested.

TABLE I: New Files and Reamers

Manufacturer	Severely or Moderately Coated	Minimally Coated
Company A Files	3	27
Company A Reamers	6	24
Company A Hedstrom Files	12	18
Company B Files	10	20
Company B Reamers	20	10
Company B Hedstrom Files	2	28
Company C Files	14	16
Company C Reamers	10	20
Company C Hedstrom Files	18	12

($\chi^2 = 45.34$; df = 8; p = <.001)

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1. Perkins, J. J.: Principles and Methods of Sterilization. Springfield, 1956, Charles C. Thomas, p. 129.

2. Cochran, W. B.: Some methods for strengthening the common Chi-square test, Biometrics 10:447, 1954.

FIGURE 1 Instrument holder designed for orientation of the instruments.

FIGURE 2 Colloidal debris, grease or oil film found on new instruments (orig mag X37.5)

FIGURE 3 Excess plastic from the handle coating the flutes of a Hedstrom file (orig mag X37.5).

FIGURE 4 Hedstrom files with a section of foam rubber caught within the flutes (orig mag X37.5).

FIGURE 5 File with epithelial cells debris (orig mag X37.5).

FIGURE 6 Frequent metal spurs such as the one shown here were found in new files (orig mag X37.5).

FIGURE 7 Hedstrom file with a frequently found barbed tip (orig mag X37.5).

FIGURE 8a Portion of a file close to D_2 which was not properly twisted (orig mag X37.5).

FIGURE 8b File with too tight of a twist which is an area of possible fracture (orig mag X37.5).

FIGURE 9 The comparison of reamers from three different manufactures. Notice the variations in flute design (orig mag X9). *Company A; "Company B; 'Company C.

FIGURE 10 The quantity of salt crystals deposited on the surface of a file during sterilization in the hot salt sterilizer (orig mag X37.5).

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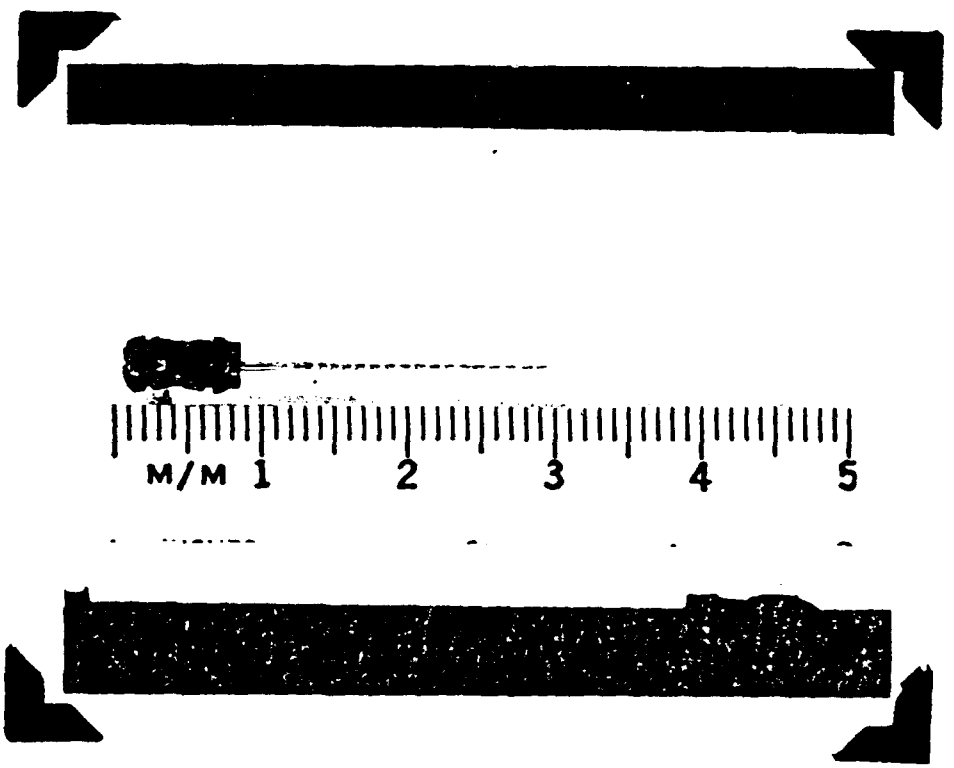


FIGURE 1

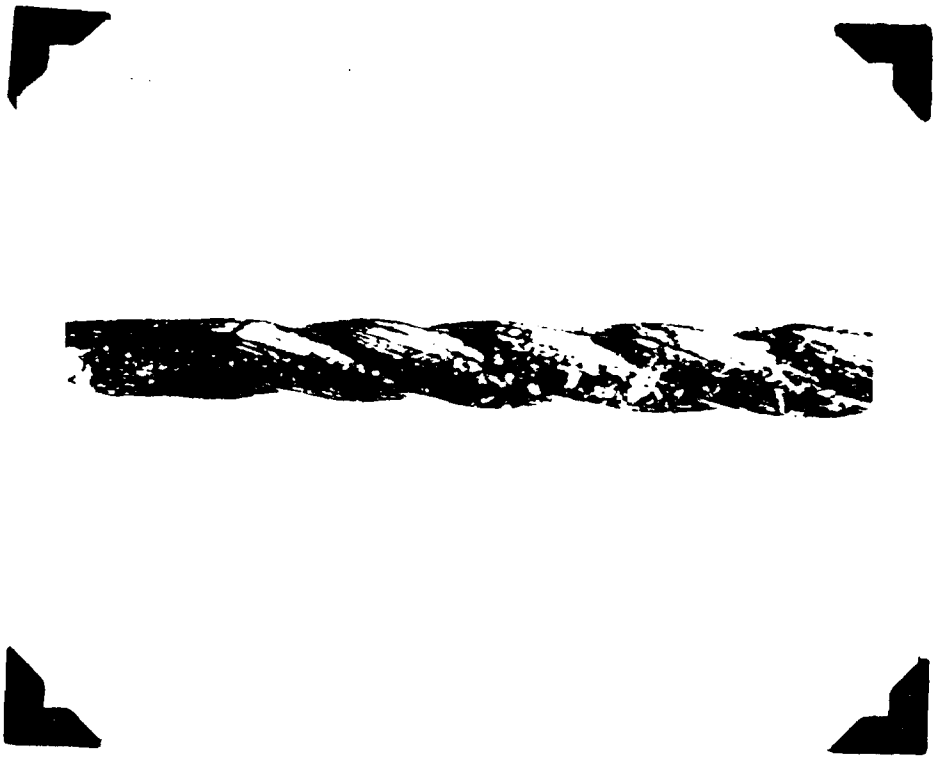
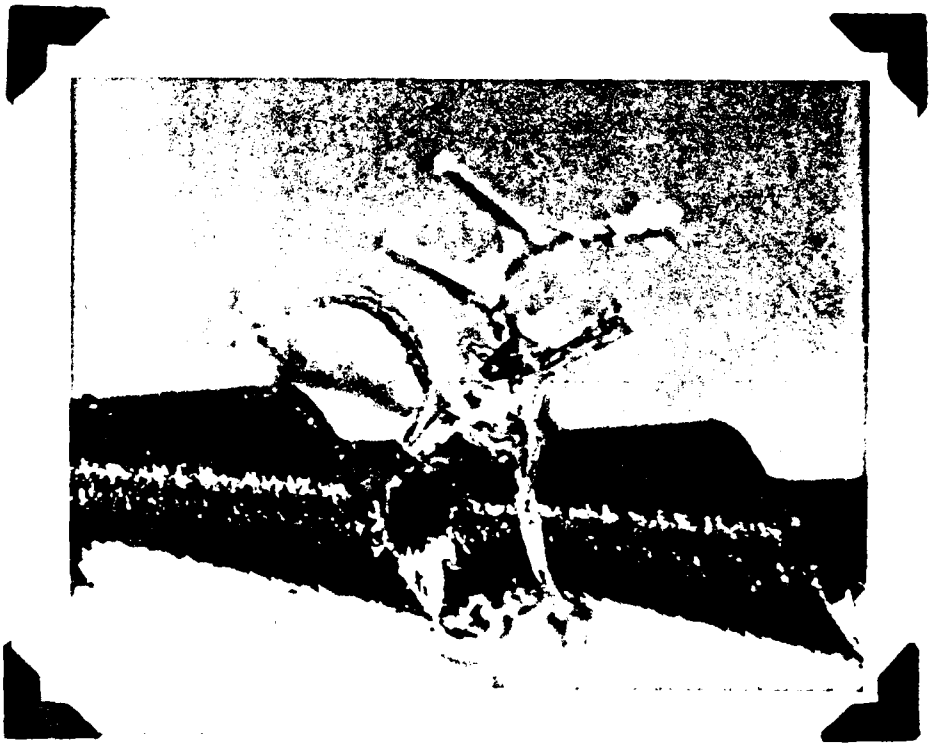


FIGURE 2

FIGURE 3



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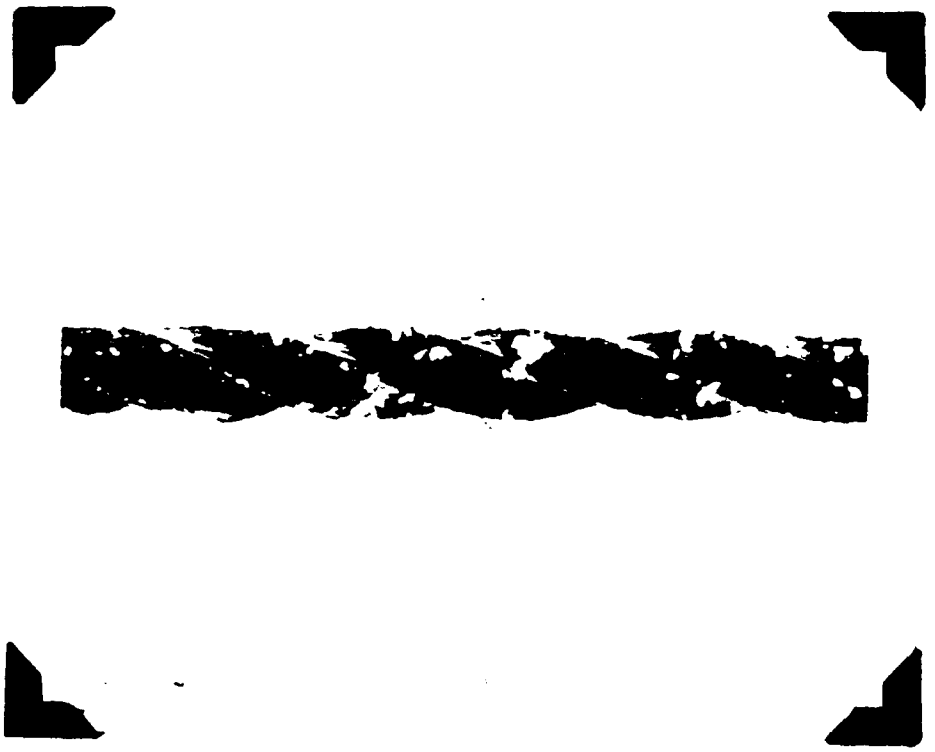

FIGURE 5

FIGURE 6

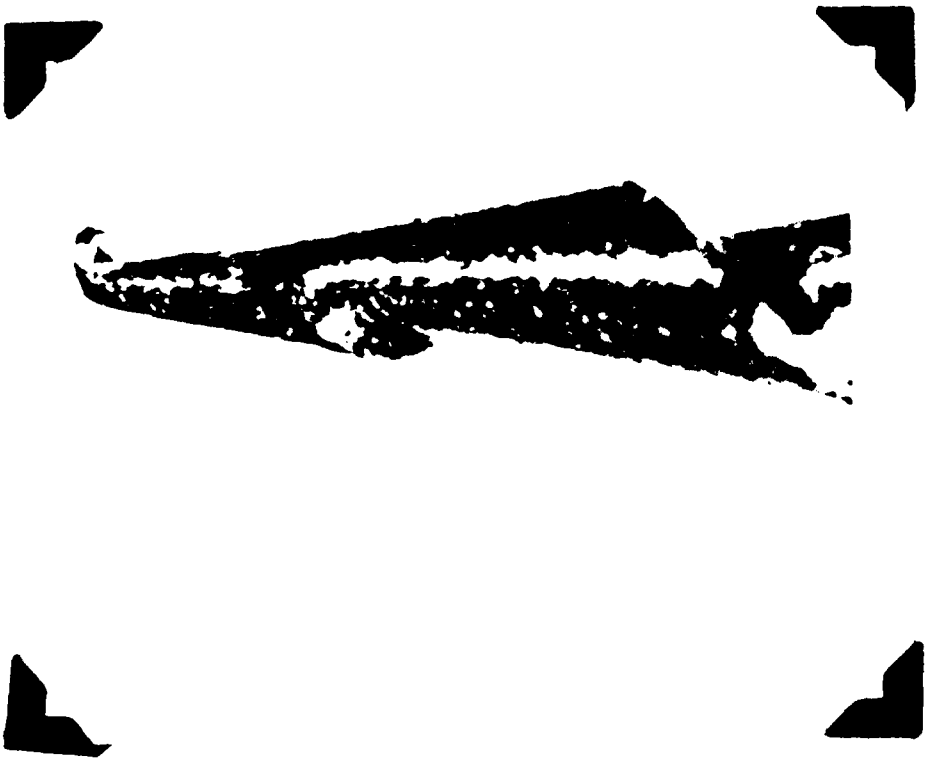

FIGURE 7

FIGURE 8a

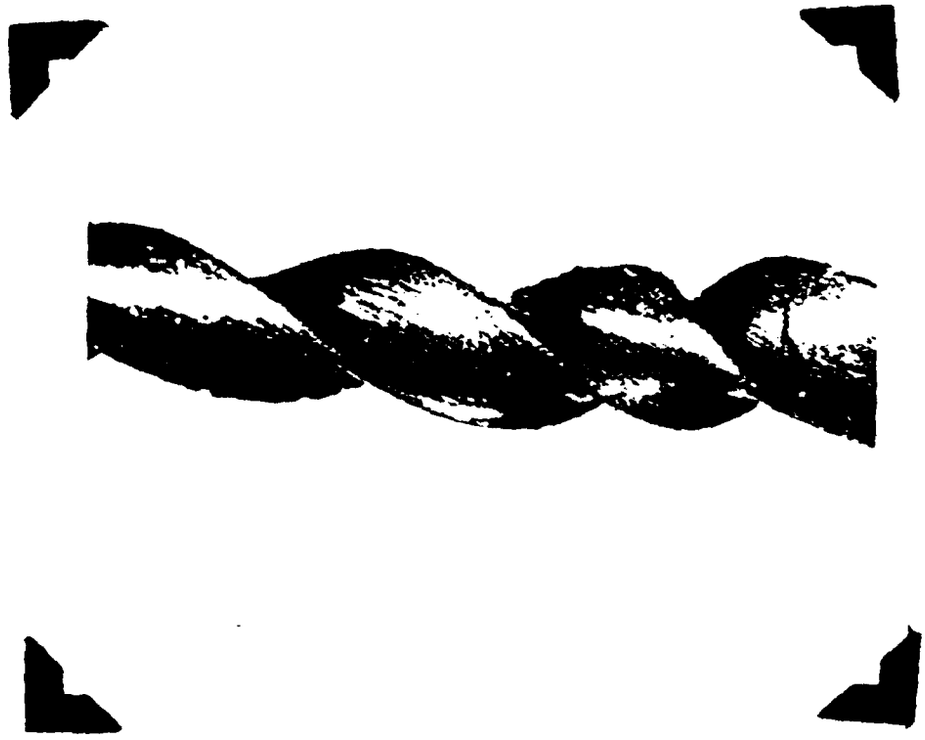

FIGURE 8b

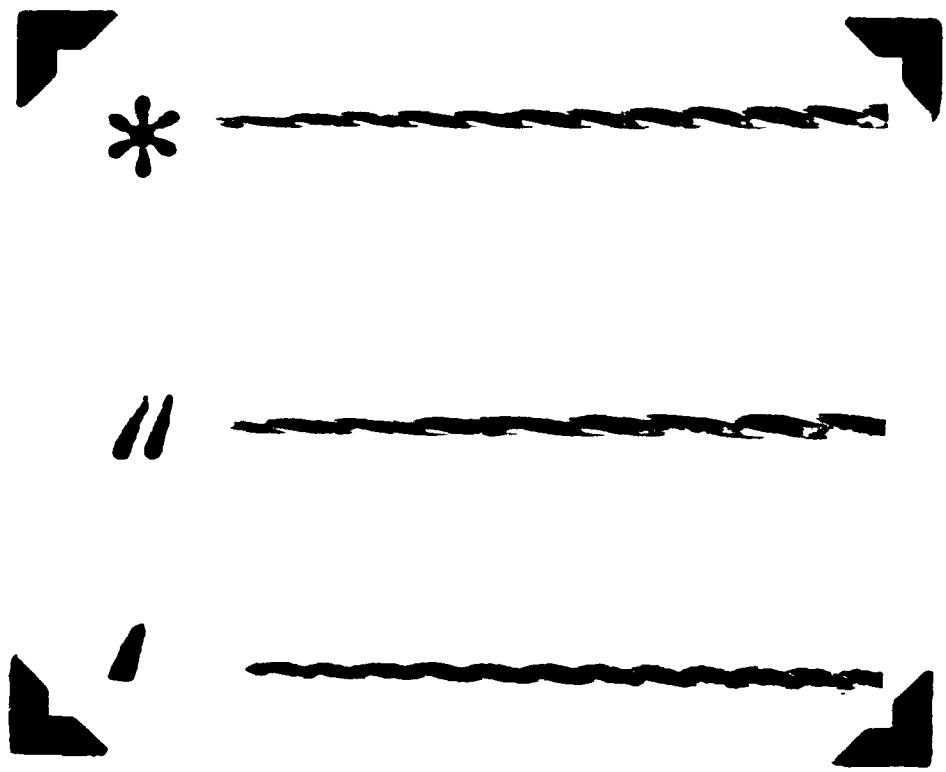

FIGURE 9

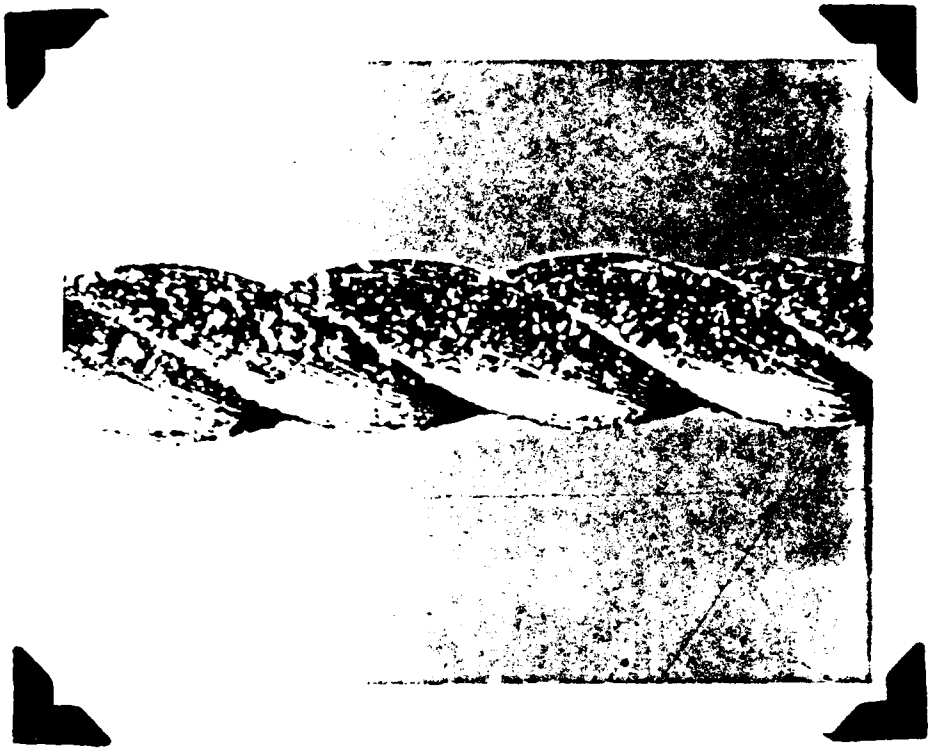

FIGURE 10